

§ 862.1790

§ 862.1790 Uroporphyrin test system.

(a) *Identification.* A uroporphyrin test system is a device intended to measure uroporphyrin in urine. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2308, Jan. 14, 2000]

§ 862.1795 Vanilmandelic acid test system.

(a) *Identification.* A vanilmandelic acid test system is a device intended to measure vanilmandelic acid in urine. Measurements of vanilmandelic acid obtained by this device are used in the diagnosis and treatment of neuroblastoma, pheochromocytoma, and certain hypertensive conditions.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2308, Jan. 14, 2000]

§ 862.1805 Vitamin A test system.

(a) *Identification.* A vitamin A test system is a device intended to measure vitamin A in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of vitamin A deficiency conditions, including night blindness, or skin, eye, or intestinal disorders.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2308, Jan. 14, 2000]

§ 862.1810 Vitamin B₁₂ test system.

(a) *Identification.* A vitamin B₁₂ test system is a device intended to measure vitamin B₁₂ in serum, plasma, and

21 CFR Ch. I (4–1–10 Edition)

urine. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

(b) *Classification.* Class II.

§ 862.1815 Vitamin E test system.

(a) *Identification.* A vitamin E test system is a device intended to measure vitamin E (tocopherol) in serum. Measurements obtained by this device are used in the diagnosis and treatment of infants with vitamin E deficiency syndrome.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38788, July 25, 2001]

§ 862.1820 Xylose test system.

(a) *Identification.* A xylose test system is a device intended to measure xylose (a sugar) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of gastrointestinal malabsorption syndrome (a group of disorders in which there is subnormal absorption of dietary constituents and thus excessive loss from the body of the nonabsorbed substances).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2308, Jan. 14, 2000]

§ 862.1825 Vitamin D test system.

(a) *Identification.* A vitamin D test system is a device intended for use in clinical laboratories for the quantitative determination of 25-hydroxyvitamin D (25-OH-D) and other hydroxylated metabolites of vitamin D in serum or plasma to be used in the assessment of vitamin D sufficiency.

(b) *Classification.* Class II (special controls). Vitamin D test systems must comply with the following special controls:

(1) Labeling in conformance with 21 CFR 809.10 and